



NDA 19-722/S-006

Questcor Pharmaceuticals, Inc.  
Attn: Matthias C. Kurth, M.D., Ph.D.  
Vice President Medical Affairs  
3260 Whipple Road  
Union City, CA 94587

Dear Dr. Kurth:

Please refer to your supplemental new drug application dated February 20, 2003, received February 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nascobal (cyanocobalamin) Gel for Intranasal Administration.

This supplemental new drug application provides for the clarification of the INDICATIONS AND USAGE statement of the package insert for Nascobal Gel for Intranasal Administration.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

Change the spelling of (b)(4)----- to “vitamin” and (b)(4)----- to “deficiencies” in the second paragraph of the **INDICATIONS AND** □ --ection.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed package insert (package insert submitted February 20, 2003). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-722/S-006". Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.  
Director  
Division of Metabolic and Endocrine Drug Products (HFD-510)  
Office of Drug Evaluation II  
Center for Drug Research and Evaluation

Enclosure: Package Insert

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Eric Colman  
8/21/03 03:30:07 PM  
Eric Colman for David Orloff